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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,762	12/28/2000	Kazuyuki Yanase	K0208.014	5214
38492	7590	02/23/2004	EXAMINER	
WILKIE FARR & GALLAGHER LLP INTELLECTUAL PROPERTY LEGAL ASSISTANTS 787 SEVENTH AVE NEW YORK, NY 10019-6099			SAYOC, EMMANUEL	
		ART UNIT	PAPER NUMBER	
		3746	DATE MAILED: 02/23/2004	

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	W
	09/720,762	YANASE ET AL.	
	Examiner	Art Unit	
	Emmanuel Sayoc	3746	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 06 February 2004.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-3 and 6-11 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-3 and 6-11 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 09 February 2004 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.  
 5) Notice of Informal Patent Application (PTO-152)  
 6) Other: \_\_\_\_\_.

**DETAILED ACTION**

1. This office action is in response to the amendments received 2/06/2004, paper 15. Claim prosecution is re-opened under the applicant's request for continued examination, 2/06/2004 paper 14. In making the below rejections and/or objections the examiner has considered and addressed each of the applicants arguments.

*Drawings*

2. Proposed amendments to the drawings received 2/09/2004 are accepted. New Formal drawings are required.

*Claim Objections*

3. Claim 11 is objected to because of the following informalities: "lure" in line 2 is misspelled. Appropriate correction is required.

*Claim Rejections - 35 USC § 103*

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 3, and 6-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trull et al. (U.S. 6,080,136), and in further view of Ito (U.S. 5,063,025).

With respect to claims 1, and 6-8, Trull et al., in Figure 6, disclose a syringe gasket (70) wherein a peripheral side surface (80) of the gasket is in contact with an inner surface of the syringe barrel (60). A restriction (labeled by the examiner on Figure 6 attached to the end of this office action) is provided, and a periphery of a bottom surface of the gasket that is not in contact with the liquid if formed into a tapered slant (also labeled by the examiner on Figure 6).

The Trull et al. differs from the claimed invention in that there is no disclosure of one or both of the peripheral side surface that is in contact with an inner surface of the syringe barrel and a surface of the gasket that is in contact with the liquid is laminated with polyethylene fluoride resin. Ito, in column 5 lines 1-7, discloses that a syringe gasket is commonly coated with a thermoplastic resin such as polyethylene or polypropylene (TEFLON). Such material is optimum in that it eliminates the need for a lubricant and serves as a protective coating for the gasket. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Trull et al. gasket by using a gasket material of polyethylene or polypropylene, in order to achieve optimum gasket lubrication, functionality, and protection within a syringe device.

With respect to claim 3, the Trull et al. apparatus comprises a tapered slant with a first and second plunger diameter. The examiner has labeled these embodiments on the marked up Figure 6.

The Trull et al. differs from the claimed invention in that there is no disclosure of the first and second diameter of the tapered slant having a difference between about .5mm and about 5mm. Furthermore, with respect to claims 6-8, there is no disclosure of the gasket's inner diameter, its height, its first diameter, or its second diameter. With respect to the specified

gasket dimensions in the claim 3 and 6-8, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Swain et al.*, 33 CCPA (Patents) 1250, 156 F.2d 239, 70 USPQ 412; *Minnesota Mining and Mfg. Co. v. Coe*, 69 App. D.C. 217, 99 F.2d 986, 38 USPQ 213; *Allen et al. v. Coe*, 77 App. D.C. 324, 135 F.2d 11, 57 USPQ 136.

6. Claim 2 rejected under 35 U.S.C. 103(a) as being unpatentable over Trull et al., as modified by Ito, as applied to claim 1, and in further view of Akaike et al. (U.S. 5,061,247).

Trull et al., as modified by Ito, set forth a device as described above, which is substantially analogous to the claimed invention. The Trull et al. device differs from the claimed invention in that there is no disclosure of the hardness of the gasket being between 55 to 60 (JIS hardness meter). Akaike et al., in column 5 lines 58-59, disclose, that a hardness of JIS of 20-85 is optimal for gaskets applied to syringe devices. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the Trull et al., as modified by Ito, gasket by using a gasket material of 20-85 JIS hardness in order to achieve optimum gasket functionality within a syringe device.

With respect to claims 9 and 10, a second tapered slant is formed between the peripheral side surface of the gasket that is in contact with an inner surface of the syringe barrel and the restriction. The gasket tightly closing the liquid is an obvious requirement for the syringe to pump fluid properly. A recitation with respect to the material intended to be worked upon by a claimed apparatus does not impose any structural limitations upon the claimed apparatus, which differentiates it from the prior art apparatus satisfying the structural limitations of the claims, as is the case here.

7. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Trull et al., as modified by Ito, as applied to claims 1 or 9, and in further view of Higashikawa (U.S. 5,830,193).

Trull et al., as modified by Ito, set forth a device as described above, which is substantially analogous to the claimed invention. The Trull et al. device differs from the claimed invention in that there is no disclosure of the syringe including a lure lock. Higashikawa in Figure 1a-1c teaches that lure lock mechanisms (37, 30, 22) have been especially common in medical syringes (21) for mounting needles (32). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the Trull et al., as modified by Ito, device by incorporating the lure locking mechanism, as taught by Higashikawa, in order to allow for needle mounting.

#### *Response to Arguments*

8. Applicant's arguments filed 2/06/2004 have been fully considered but they are not persuasive. The applicant claims that the combination of Trull et al. and Ito is improper on the grounds that the Ito device is directed to a syringe for liquid chromatography, and that the Ito device addresses fluid pumping difficulties other than that of injecting liquid into the human body such as leakage due to heat and pressure of sterilization. The combination is directed to applying a polyethylene or polypropylene, TEFLON, lamination on the plunger, as taught by Ito, onto the Trull et al. device. Ito teaches that this coating is intended to protect the plunger from any adverse effects of the pumped fluid. The examiner holds that both references are within the field of the applicant's endeavor. Intended use of the invention holds no weight in structural

patentability of the claimed invention. Applying the TEFLON coating to the Trull et al. does have obvious advantages, does not destroy the Trull et al. device, and is fully capable of carrying out the intended use of the claimed invention. The applicant in the disclosure states that in prior-art, TEFLON coating in plungers is directed at providing a virtually frictionless sliding motion of the plunger. However, the applicant's specification, does not say why a TEFLON coating is provided over the plunger, only that one exists. One can assume the applicant is using the TEFLON coating for the same purpose as stated in the background art. However, one of ordinary skill in the art at the time the invention was made would have known that TEFLON is not only ideal in creating a reduced friction sliding surface, but also it provides a protective seal on the plunger. No lubrication on the plunger is critical in preventing contaminating fluids injected into the body. Also the protective seal allows for the plunger to be easily sterilized. Furthermore the Ito device, directed at supercritical fluid pumping applications, which involves extreme temperature and pressure conditions would have been well suited for medical purposes.

With respect to the particular hardness in the claimed invention, the Akaike et al. reference provides a well-known range of plunger hardness. Following this range would have been pertinent to applicant's field of endeavor. Also, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Swain et al.*, 33 CCPA (Patents) 1250, 156 F.2d 239, 70 USPQ 412; *Minnesota Mining and Mfg. Co. v. Coe*, 69 App. D.C. 217, 99 F.2d 986, 38 USPQ 213; *Allen et al. v. Coe*, 77 App. D.C. 324, 135 F.2d 11, 57 USPQ 136.

***Conclusion***

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following references are cited to further show the state of the art with respect to gaskets for syringes.

U.S. Pat. 5, 688, 252 to Matsuda et al.

U.S. Pat. 5, 397, 313 to Gross

U.S. Pat. 4, 303, 070 to Ichikawa et al.

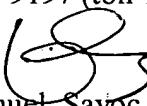
The applicant is invited to note the tapered slants in the listed references.

***Contact Information***

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emmanuel Sayoc whose telephone number is (703) 305-0054. The examiner can normally be reached on M-F 8 A.M. - 6 P.M..

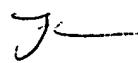
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (703)308-2675. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Emmanuel Sayoc  
Examiner  
Art Unit 3746

ECS



JUSTINE YU  
SUPERVISORY PATENT EXAMINER  
2/21/04